A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff

Draft Guidance – Not for Implementation

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Premarket Notifications Staff
Program Operations Staff
Office of Device Evaluation

Preface

Public Comment:

For 60 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Background

FDA is conducting a pilot premarket review program and is soliciting participation from the medical device industry. The pilot program is intended to assess the feasibility of a proposed internationally harmonized format and content for premarket submissions, e.g., premarket notification (510(k)) submissions and premarket approval (PMA) applications. The proposed document is entitled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)."

This premarket pilot initiative has its origins in the recommendations of the Global Harmonization Task Force (GHTF), Study Group 1. The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The organization, goals, and procedures of the GHTF are described on the GHTF internet web site http://www.ghtf.org.

What documents are needed to implement the pilot program?

The documents generated by Study Group 1 and FDA for implementing the pilot program include the following:

- the FDA draft guidance document for the pilot (this document)

  The FDA draft guidance document is intended to assist the medical device industry in completing a premarket submission using the draft STED format and in accordance with United States requirements.

- Appendix 1: a letter of announcement to the global medical device industry

The announcement letter summarizes the proposed pilot premarket program.

- Appendix 2: the GHTF Study Group 1 draft STED document

  The draft STED document describes an internationally harmonized format and content for premarket submissions, e.g., PMA applications and 510(k) submissions, based on conformity to "Essential Principles."

- Appendix 3: the GHTF document entitled "Essential Principles of Safety and Performance of Medical Devices"

  The Essential Principles are a GHTF-derived list of both general and specific safety and performance recommendations for medical devices.

What divisions in the Office of Device Evaluation are participating in the pilot program?

Two Office of Device Evaluation divisions will be the primary participants in the pilot program: the Division of Dental, Infection Control, and General Hospital Devices (DDIGD) and the Division of Reproductive, Abdominal, and Radiological Devices (DRARD). Because of current workload considerations, two other divisions will participate in this pilot in a more limited manner: the Division of Cardiovascular and Respiratory Devices (DCRD) and the Division of General, Restorative, and Neurological Devices (DGRND).

How will the pilot be implemented in the participating divisions?

DDIGD and DRARD will accept PMA applications and 510(k) submissions in the draft STED format instead of the customary format for certain types of devices from those manufacturers who want to participate in the pilot program. Table 1 lists the generic types of devices for DDIGD and DRARD that are candidates for the pilot program.

Manufacturers should continue to submit PMA applications and 510(k) submissions to DCRD and DGRND in the customary format described in current FDA regulations. However, these two divisions will each work with up to four manufacturers to do a parallel review of parts of these applications that will also be submitted in the draft STED format. This concurrent review of the current FDA and proposed STED formats of the same application will help these divisions assess the GHTF document without reducing review times. FDA does not expect that the submission of portions of the PMA application or 510(k) in an additional form (the draft STED format) will be burdensome because many manufacturers of these devices will be preparing submissions for other countries using the draft STED format. For the concurrent submissions, FDA is interested in evaluating how the data and information submitted in the customary format would be reformatted for a STED. A complete concurrent submission using the draft STED format may not be necessary. Instead, only the initial volume of a submission in the draft STED format for a PMA application or

complex 510(k) submission may suffice. Table 1 lists the generic types of devices that will be considered by DCRD and DGRND for the pilot program.

Table 1 Candidate Devices for the Pilot Premarket Program

Division	Device Type
Primary Division Participants, draft STED format in lieu of customary format	
DDIGD	Intravascular Catheters
	Administration Sets
	External Infusion Pumps
	Endosseus Dental Implants
	Surgical Drapes
DRARD	Hemodialyzers and Hemodialysis Catheters
	Plasma Cell Separators for Therapeutic Use
	Bone Densitometers
	Fluoroscopic X-ray
	Urological Catheters
Limited Participation, customary format concurrent with draft STED format (e.g., initial volume)	
DCRD	ECG Monitors
	PTCA Catheters
	Coronary Stents
	Anesthesia Catheters and Needles
	Pacing Leads
DGRND	Orthopedic Implants

FDA is asking persons who intend to submit PMA applications or 510(k) submissions to DDIGD, DRARD, DCRD, or DGRD to consider participating in the pilot program. The pilot program will not include premarket submissions for Special 510(k)s, product development protocols, humanitarian device exemptions, or submissions already reviewed by Third Parties.

II. Purpose

This FDA guidance document supplements the draft STED document as follows:

1. It provides administrative instructions to medical device manufacturers who are using the draft STED document for a 510(k) submission or PMA application.

2. It describes current data and information that should be included in a 510(k) submission or PMA application, in addition to the documentation described in the draft STED document.

3. It includes tables that compare the differences between the draft STED document and the submission requirements in the PMA and 510(k) regulations.

III. Administrative Instructions

Persons who intend to submit a 510(k) submission or a PMA application and are interested in participating in the pilot program should:

- Ensure that the candidate medical device is subject to premarket review by FDA, i.e., it is not a Class I or a Class II exempt device.

- Verify that your medical device is a candidate for a PMA or a traditional or abbreviated 510(k). Special 510(k)s, Humanitarian Device Exemptions, 510(k)s already reviewed by a Third Party, and Product Development Protocols are not included in this pilot program. For definitions and more information on traditional, abbreviated, or special 510(k) submissions, refer to the FDA guidance document entitled, "The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" http://www.fda.gov/cdrh/ode/parad510.pdf.

- Verify that your medical device is identified in Table 1.

- Notify one of the persons identified in Part VI below of your intent to submit either a 510(k) submission or PMA application to DDIGD or DRARD using the draft STED format, or if you intend to submit a concurrent submission (e.g., initial volume) using the draft STED format to DCRD or DGRND. He/she will inform you whether or not FDA will accept and evaluate your submission or application.

- Submit your complete submission to DDIGD or DRARD in the format described in the draft STED document, or customary and concurrent submissions (e.g., initial volume) to DCRD or DGRND. Include any additional required information described in Part IV below, either in the cover letter as indicated or as additional sections of your submission using the draft STED format.

- Submit documents to the Document Mail Center HFZ-401, 9200 Corporate Blvd., Rockville, MD 20850.

- Clearly identify on the cover page, in bold large print, **Global Harmonization Pilot 510(k) or PMA**.

IV. Information required in a 510(k) or PMA compared to draft STED document recommendations

For 510(k)s:

Include the following additional information:

- Trade name and classification name of the device
- Establishment registration number, if one is available
- Device class or a statement that the device is not yet classified
- Truthful and Accurate Statement
- Indications for Use Enclosure
- SMDA Summary or Statement
- Class III Certification and Summary (for all Class III devices under 510(k) authority)
- Financial Certification or Disclosure Statement for 510(k)s including a Clinical Study.
- Name and Address of Manufacturing Facility for Class III 510(k)s

Table 2 provides a comparison between 21 CFR 807.87, Information required in a premarket notification submission, and the draft STED document.

TABLE 2: Comparison of the 510(k) Regulation to the Draft STED Document

510(k) Regulation (21 CFR 807.87)	**Corresponding STED Section**
(a) Trade or proprietary name, and common or usual name	Referred to as "cover page information" in Annex C.2. Follow 510(k) regulation.
(b) Establishment Registration Number	
(c) Class	
(d) Performance Standards	Section 7.1.2. and 7.3.1.
(e) Labels and labeling	Section 7. 4.
(f) Comparison of features	Section 7. 2.
(g) Supporting data	Section 7. 3. And 7.5
(h) 510(k) Summary	Referred to as "country-specific information" in Annex C.1. Follow 510(k) regulation.
(i) Financial Certification or Disclosure Statement	
(j) Class III Summary	
(k) Truthful and Accurate Statement	

Note: Section 7.6 of the GHTF draft STED document, which addresses manufacturing information, is ordinarily not required for a 510(k) submission.

For PMAs:

Include the following additional information:

- Applicant's name and address
- Table of contents
- Summary of Safety and Effectiveness
- Justification for a single investigator
- Samples
- Environmental assessment
- Financial certification or disclosure statement

Table 3 provides a comparison between 21 CFR 814.20, Premarket Approval Application, and the draft STED document.

TABLE 3: Comparison of the PMA Regulation to the Draft STED Document

PMA Regulation (21 CFR 814.20)(b)	**Corresponding STED Section**
(1) Applicant's Name & Address	Referred to as "cover page information" in Annex C.2. Follow PMA regulation.
(2) Table of Contents	
(3) Summary of Safety and Effectiveness	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(4) Device Description	Section 7.2., 7.5, 7.6.
(5) Performance or Voluntary Standard	Section 7.1.2., 7.3.1.
(6) Results of non-clinical studies and clinical investigations involving human subjects	Section 7.3.1., 7.3.2.
(7) Justification for a single investigation	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(8) Bibliography	Section 7.3.2.
(9) Samples of the device	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(10) Proposed Labeling	Section 7.4.
(11) Environmental Assessment	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(12) Financial Certification or Disclosure Statement	

V. Important Information about the Pilot Premarket Program

Four of the founding members of the GHTF are participating in the pilot program. They are the United States, Canada, Australia, and the European Union. Each of the participants will provide specific directions for implementing the pilot program within its jurisdiction.

The GHTF wants to assess the international utility of the draft STED document. Therefore, SG1 of the GHTF encourages manufacturers to prepare and submit, if submission is required, STEDs for the same device to as many of the four participating GHTF member countries as possible. SG1 also encourages manufacturers to try the STED format for different classes of devices that are candidates for the pilot program.

FDA intends to process premarket submissions in the GHTF harmonized format within statutory time limits and with review times comparable to other submissions for similar products. There will be no expedited review of submissions, unless the device merits such a process under current policies.

FDA plans to conduct the pilot program for one year. The pilot program will begin on the date of publication of the final FDA guidance document. FDA will assess how the pilot is proceeding during its course and may choose to decline receipt of additional submissions using the draft STED format in order to assess the initial experiences. At the end of the pilot, FDA and other GHTF participants will analyze the outcome to determine whether the draft STED document is a viable alternative to current premarket submission procedures, and if the program should be continued or expanded. FDA will post a report of the outcome of the pilot program on its Internet web site.

VI. Contacts

If you are interested in participating, or have questions regarding the pilot program, please contact one of the following individuals:

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